

REMARKS

Entry of the foregoing, and further and favorable reconsideration, in light of the foregoing amendments and the following remarks, are respectfully requested.

By the present Amendment, Claim 50 has been amended to delete reference to "soluble receptors for interferon- γ ". Claim 51 has been amended to delete reference to an acellular component, which lacks antecedent basis in Claim 50 as previously amended, and to recite that the targeted immune system inhibitor is present in a plasma component of the blood or fraction thereof. Claim 81 has been amended to incorporate the recitations of withdrawn Claim 81. No new matter has been added.

In the Official Action, the Examiner objected to Claim 50, and thus Claims 51-74 and 83-86, dependent thereon, alleging that Claim 50 required the word "and" before "a conduit". The Examiner's attention is respectfully drawn to page 2 of the Preliminary Amendment and Response to Restriction Requirement dated May 19, 2004, in which on line 15, just before "b) a conduit" is inserted the underlined word "and". As such, no correction is deemed to be necessary. Withdrawal of the objection is therefore respectfully requested.

The Examiner rejected Claims 51 and 81 under 35 U.S.C. §112, second paragraph, citing correction of antecedent basis to amended Claim 50, and Claim 80, respectively. With respect to Claim 51, this claim has been amended to refer to the fact that "the targeted immune system inhibitor is present in a plasma component of the blood or fraction thereof" in amended Claim 50. With respect to Claim 81, this claim has been amended to incorporate the recitation of withdrawn Claim 80. While the Examiner correctly noted that Claim 80, from which Claim 81 depended, had

been withdrawn as a result of the Restriction Requirement, the rejections under 35 U.S.C. §103(a) list Claim 80 as rejected. Applicants assume that the reference to Claim 80 in those rejections was an inadvertent error, and as such, Claim 80 will not be addressed in Applicants' response to the rejections under 35 U.S.C. §103(a).

Claims 50-74, 81 and 83-86 are currently under consideration.

The Examiner rejected the claims under 35 U.S.C. §103(a) as being purportedly unpatentable as follows:

- (1) Claims 50, 51, 60-65, 69-74, [80]¹ and 81 over Skurkovich, 5,626,843 ("Skurkovich '843"), in view of Greenblatt;
- (2) Claims 50, 51, 60-65, 69-74, [80]¹ and 81 over Skurkovich '843, in view of Yelavarthi;
- (3) Claims 52, 54, 58, 83-86 over Skurkovich, 5,626,843, in view of Greenblatt, and further in view of Skurkovich 4,362,155 ("Skurkovich '155"); and
- (4) Claims 53, 55-57 and 59 over Skurkovich '843, in view of Greenblatt, and further in view of Skurkovich '155, and further in view of Prusiner et al, 6,221,614.

These rejections are respectfully traversed.

The presently claimed invention relates to an extracorporeal system for reducing the amount of a targeted immune system inhibitor in blood, wherein the targeted immune system inhibitor is selected from the group consisting of:

- soluble receptors for tumor necrosis factor α and β ,
- interleukin-1 receptor antagonist,
- soluble receptors for interleukin- 1, and
- soluble receptors for interleukin-6.

The Examiner relies in each of her rejections, on Skurkovich '843, as allegedly teaching the removal of receptors for tumor necrosis factor (TNF). However, Skurkovich '843 only discloses that receptors for tumor necrosis factor can be removed in combination with removal of interferon (IFN) or receptors thereto:

“An objective of the present invention is to restore immunity...by removing IFNs together with TNF, and in some cases the receptors therefor...” (Col. 2, ll. 60-63);

“a combined sorbent comprising a first component of antibodies to IFNs, a second component ...and a third component to remove TNF can be used.” (Col. 3, ll. 3-7); and

“the invention uses one sorbent for removing IFNs and other substances, often together with their receptors...” (Col. 3, ll. 18-21).

Indeed, the Examples of Skurkovich '843 all relate to preparation of interferon antibodies and columns, and all of the claims of Skurkovich '843 recite that removal of interferon or an interferon receptor is an essential element: (1) a first antibody to interferon, and a second antibody to tumor necrosis factors, and receptors therefor (see Claims 1-9) or (2) one anti-interferon antibody or an antibody to alpha interferon receptor and one anti-gamma interferon antibody or an antibody to gamma interferon receptor (see Claims 10-16). As such, there would have been no motivation for a person of ordinary skill in the art to attempt to stimulate an immune response in the absence of removal of interferon.

The invention as presently claimed excludes the additional removal of interferon, because the claims recite that the “at least one binding partner” binds to

¹ Claim in bracket was indicated by the Examiner to be withdrawn from further consideration.

molecules "selected from the group consisting of: soluble receptors for tumor necrosis factor α and β , interleukin-1 receptor antagonist, soluble receptors for interleukin- 1, and soluble receptors for interleukin-6". Skurkovich '843 does not disclose or suggest that immunity could be restored in the absence of concurrent removal of interferon or receptors thereto.

The additional references cited by the Examiner do not cure the deficiencies of Skurkovich '843. Greenblatt and Yelavarthi are relied upon by the Examiner only to support her allegation that antibodies to TNF- α exist (see, Official Action at p. 5, third paragraph, and p. 9, second full paragraph, respectively). Like Skurkovich '843, Skurkovich '155 discloses "an absorption system to absorb interferon..." and does not even mention tumor necrosis factor, interleukin, or receptors thereto. Prusiner discloses the removal of prions from the blood, and does not even mention tumor necrosis factor, interleukin, or receptors thereto.

As such, none of the cited references, alone or in combination, discloses or suggests a system for the removal of soluble receptors for tumor necrosis factor α and β , interleukin-1 receptor antagonist, soluble receptors for interleukin- 1, and soluble receptors for interleukin-6, in the absence of removal of interferon or receptors thereto. Withdrawal of these rejections are therefore respectfully requested.

In view of the foregoing, it is believed that the claims are in condition for allowance, and early and favorable action in the form of a notice of allowance is respectfully requested.

In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney at (703) 836-6620.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: February 7, 2005

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

By: Sharon E. Crane
Sharon E. Crane, Ph.D. *by R.D. Huntington*
Registration No. 36,113 *Reg. No. 27,903*